

2010 Data Protection Seminar

TMA Privacy Office



The New Frontier: ARRA/HITECH Privacy and Security Changes



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The New Frontier: ARRA/HITECH Privacy and Security Changes

Purpose

Provide an overview of provisions of the American Recovery and Reinvestment Act (ARRA) that amend and expand privacy and security requirements; these and other provisions relating to health information technology (HIT) are known as the Health Information Technology for Economic and Clinical Health (HITECH) Act



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Objectives

- Upon completion of this presentation, you should be able to:
 - Identify key provisions of the HITECH Act
 - Describe HITECH privacy and security changes
 - Discuss impact on the Military Health System (MHS)



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ARRA

- Signed into law February 12, 2009 (“Stimulus Bill”)
- Designed to stimulate the economy through investments in infrastructure, unemployment benefits, transportation, education, and health care
- Division A, Title XIII and Division B, Title IV: HITECH Act



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HITECH Act: Sorting it Out

- Title XIII: HIT
 - Subtitle A: Promotion of HIT – Universal electronic health record (EHR) by 2014
 - Subtitle B: Testing of HIT – Financial incentives for adoption
 - Subtitle C: Grants and Loan Funding – HIT infrastructure and use
 - Subtitle D: Privacy – Privacy Rule and Security Rule
- Title IV: Medicare and Medicaid (HIT) – Incentives for adoption and “meaningful use” of certified EHR technology



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HITECH Act: Sorting it Out (continued)

- Most provisions effective February 17, 2010
- Other effective dates depend on issuance of regulations or guidance
- Broadens scope and applicability of Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules to Business Associates (BAs)
- Provides new breach notification requirements



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HITECH Act: Sorting it Out (continued)

- Tightens restrictions on use and disclosure of protected health information (PHI)
- Strengthens individual privacy rights
- Strengthens compliance oversight, enforcement, and penalties for violations



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Enforcement and Penalty Provisions

- Criminal penalties can be applied to individuals (employees)
- New system of civil monetary penalties
- Required investigation and penalties if “willful neglect”
- Civil action by State Attorneys General
- Periodic compliance audits by the Department of Health and Human Service (HHS): In August 2009 the HHS Office of Civil Rights (OCR) was assigned enforcement of the HIPAA Security Rule

Penalty Amount	Prior to February 18, 2009	On/after February 18, 2009
	Up to \$100 per violation	\$100 to \$50,000 per violation
Calendar Year Cap	\$25,000	\$1.5 M



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Enforcement and Penalty Provisions (continued)

- Impact on MHS
 - HHS enforcement role concerning DoD compliance and application of penalties unclear
 - HHS OCR not enforced penalties in the past, but has requested compliance information from MHS



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HITECH Act: Breach Notification

- Interim Final Rule released August 2009; effective September 2009; enforcement commenced February 2010
- Requires HIPAA covered entities (CEs) and BAs to report breaches of “unsecured” PHI
- “Unsecured” PHI: PHI that has not been encrypted or destroyed based on National Institute of Standards and Technology (NIST) standards in HHS annual guidance
 - NIST encryption standards for electronic data in use
 - NIST standards for destruction of electronic media



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HITECH Act: Breach Notification (continued)

- Breach must involve “unsecured” PHI; violate Privacy Rule
- Breach must pose significant risk of harm
- Need to conduct risk analysis
- “Burden of proof” on CE and BA of CE
- Three exclusions to breach:
 - Good faith unintentional access by authorized person
 - Inadvertent disclosure by one authorized person to another
 - Unauthorized disclosure to a person who cannot reasonably retain it



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HITECH Act: Breach Notification (continued)

- Media notification if ≥ 500 individuals in a state or jurisdiction are affected
- Concurrent HHS notification if ≥ 500 individuals; otherwise annual log to HHS
- Impact on MHS
 - Redefines “breach” from DoD 5400.11-R, “DoD Privacy Program”, definition to “unsecured” PHI; must distinguish between the two definitions
 - Quantifies number of affected individuals (≥ 500) for notification to media and HHS
 - HHS rules specify notification “without unreasonable delay” but no later than 60 days after discovery; DoD has 10-day standard for individual notification



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HITECH Act: Breach Notification (continued)

- Determination of breach
 - MHS components and MHS BAs continue to follow pre-existing DoD regulations/policies/guidance
 - TRICARE Management Activity (TMA) Privacy Office will apply breach rules to determine if HHS breach occurred
- Reporting to DoD and other federal agencies
 - Continue to follow all DoD requirements
 - All MHS breaches reported to TMA Privacy Office within 24 hours of discovery



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HITECH Act: Breach Notification (continued)

- Reporting to HHS: TMA Privacy Office will report qualifying breaches to HHS
- Media notification
 - Each MHS component responsible for establishing protocol for media notification
 - TMA Privacy Office advise MHS component when media notification required under HHS Breach Rules



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HITECH Act: Breach Notification (continued)

- Current status

- Guidance memo to Services and MHS contractors
- Frequently asked questions document posted on TMA Privacy Office Web site
- Information paper posted on TMA Privacy Office Web site
- Language drafted for DoD 6025.18-R, “DoD Health Information Privacy Regulation”, update



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HITECH Act: Business Associates

- Effective February 2010 (waiting for HHS guidance)
- BA directly subject to certain HIPAA privacy and security requirements “in the same manner that [the requirements] apply to the covered entity”
- BA must comply with HIPAA Security Rule safeguards, policies and procedures and documentation requirements
- BA must comply with the HIPAA Privacy Rule
 - Including new privacy provisions in ARRA
 - Subject to same civil and criminal penalties as a CE



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HITECH Act: Business Associates (continued)

- Impact on the MHS
 - Amendment of Business Associate Agreements (BAA) (awaiting further guidance from HHS)
 - Amended personally identifiable information (PII)/PHI standard contract language (located on TMA Privacy Office Web site)
 - Update to standard BAA language forthcoming after release of additional HHS guidance
 - HHS required to issue annual guidance on technical safeguards



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HITECH Act: Privacy Provisions

- Right to restriction
 - Effective February 2010 (awaiting HHS guidance)
 - CE must comply with individual's request for restriction if: (1) disclosure is to health plan for payment or health care operations and (2) patient pays provider "out of pocket" in full
- Right to electronic access
 - Effective February 2010 (awaiting HHS guidance)
 - If CE uses an EHR, individual has right to a copy of PHI in electronic format



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HITECH Act: Privacy Provisions (continued)

- Accounting for treatment, payment, and health care operations (TPO) disclosures
 - Earliest effective date January 1, 2011
 - If CE maintains an EHR, must include in an accounting the disclosures from the EHR for TPO for three years prior to the request
- Minimum Necessary:
 - Effective February 2010, but HHS guidance pending
 - CE will restrict use and disclosure of PHI, to extent practicable, to limited data set, or if necessary, to minimum necessary when rule applies



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HITECH Act: Privacy Provisions (continued)

- Marketing and fundraising: Additional marketing restrictions on CE where entity receives payment in exchange for communication; fundraising communications must provide opt-out to individual
- Sale of PHI: Will restrict sale of PHI unless individual provides authorization (requires regulations to be issued within 18 months)



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HITECH Act: Privacy Provisions (continued)

- Impact on the MHS
 - Strengthens individual privacy rights
 - Educate and train staff on new requirements
 - Requires update to the MHS Notice of Privacy Practices
 - Requires update to DoD 6025.18-R



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HITECH Act: Meaningful Use of EHRs

- Rules require provider compliance with certification standards for ARRA incentive payments for EHR systems
- “Meaningful Use” standards not directly relevant to MHS
- May become indirectly relevant to MHS in future as an industry standard
- EHR certification standards relevant to EHR interoperability with non-MHS systems
- January 13, 2010: HHS Centers for Medicare & Medicaid Services Interim Final Rule on EHR certification standards; plus proposed rule on “meaningful use” of EHRs



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Summary

- You should now be able to:
 - Identify key provisions of the HITECH Act
 - Describe HITECH privacy and security changes
 - Discuss impact on the MHS



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Resources

- TMA Privacy Office Website: <http://www.tricare.mil/tma/privacy>
- For access to HHS rules and guidance, go to:
<http://www.hhs.gov/ocr/privacy>
- E-mail Privacymail@tma.osd.mil for subject matter questions
- To subscribe to the TMA Privacy Office E-News, go to:
<http://www.tricare.mil/tma/privacy/maillinglist.aspx>



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